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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,201	04/25/2001	Susan Salceda	DEX-0196	2155

26259 7590 09/10/2003

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EXAMINER
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DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/10/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/807,201

Applicant(s)

SALCEDA ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,8,10,16
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claim 7.

Accordingly, claim 1, SEQ ID NOs:7-8 are examined in the instant application.

This application contains part of claim 1 drawn to an invention nonelected with traverse in Paper No.7, i.e. a method for diagnosing the presence of prostate cancer, comprising determining levels of a protein expressed by a polynucleotide comprising SEQ ID NO:7 or 8. A complete reply to the final rejection must include cancellation of nonelected claim or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### **INFORMATION DISCLOSURE STATEMENT**

Enclosed please find the signed PTO-1449 of paper Nos: 6,8,10 and 16, of 01/15/02, 06/17/02, 08/05/02 and 05/21/03, respectively.

### **OBJECTION**

1. Claim 1 remains objected to for being drawn to non-elected invention, i.e. a method for detecting prostate cancer, comprising detecting the levels of protein encoded by SEQ ID NO:7 or 8.
2. The amended claim 1 is objected to because it is not clear which "levels" are referred to.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION**

Claim 1 remains rejected under 35 USC 112, first paragraph, pertaining to lack of a clear written description for a method for detecting prostate cancer, comprising determining a change in the "levels" of a polynucleotide comprising SEQ ID NO:7 or 8 in a cell or tissue, for reasons already of record in paper No:15.

Applicant argues that identifying any additional sequence of a gene containing a polynucleotide sequence comprising SEQ ID NO:7 or 8 is routine in the art.

Applicant's arguments in paper No:18 have been considered but are found not to be persuasive for the following reasons:

As amended, the claim still reads on a method for detecting prostate cancer, comprising determining a change in the "gene levels" of a polynucleotide comprising SEQ ID NO:7 or 8 in a cell or tissue, since the claim is not limited to a method for detecting prostate cancer, comprising determining a change in the "mRNAs levels" of a polynucleotide comprising SEQ ID NO:7 or 8 in a cell or tissue, and in view of the contemplation in the instant application to detect prostate cancer by detecting the gene level of CSG (p.3, last paragraph, bridging p.4).

Applicant has not disclosed the structure of a gene containing a polynucleotide sequence comprising SEQ ID NO:7 or 8, which is a requirement for a written description, as taught by the court. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not

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required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Thus disclosure of SEQ ID NO:7 and 8 and an ability to screen for the gene comprising SEQ ID NO:7 or 8 is insufficient to describe the gene for use in the claimed method. Therefore, Applicant is not in possession of a method for detecting prostate cancer, comprising determining a change in the "levels" of a polynucleotide comprising SEQ ID NO:7 or 8 in a cell or tissue

#### **REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE**

1. Claim 1 remains rejected under 35 USC 112, first paragraph, pertaining to lack of enablement for a method for detecting prostate cancer, comprising determining a change in the "levels" of a polynucleotide comprising SEQ ID NO:7 or 8 in a cell or tissue, for reasons already of record in paper No:15.

Applicant argues that identifying a gene containing a polynucleotide sequence is routine in the art. Applicant further argues that the amendment to replace "CSG" with a polynucleotide comprising SEQ ID NO:7 or 8 " renders the claim enabled, because the instant specification discloses the full length nucleotide sequences for SEQ ID NO:7 and

Applicant's arguments in paper No:18 have been considered but are found not to be persuasive for the following reasons:

As amended, the claim still reads on a method for detecting prostate cancer, comprising determining a change in the "gene levels" of a polynucleotide comprising SEQ ID NO:7 or 8 in a cell or tissue, since the claim is not limited to a method for detecting prostate cancer, comprising determining a change in the "mRNAs levels" of a polynucleotide comprising SEQ ID NO:7 or 8 in a cell or tissue, and in view of the contemplation in the instant application to detect prostate cancer by detecting the gene level of CSG (p.3, last paragraph, bridging p.4).

It is noted that it is unpredictable that there is any change in the gene level of a gene or a polynucleotide comprising SEQ ID NO:7 or 8 in prostate cancer, because there is no correlation between the level of a gene and the level of its mRNAs, as taught by van de Vijver et al, of record. Thus it is not germane to the enablement of the claim that one could screen for the gene comprising SEQ ID NO:7 or 8. The specification however does not disclose that there is a change in the gene level of a polynucleotide comprising SEQ ID NO:7 or 8 in prostate cancer.

2. If Applicant could overcome the above 112, first paragraph, claim 1 still remains rejected under 35 USC 112, first paragraph, pertaining to lack of enablement for a method for detecting prostate cancer, comprising determining a change in the level of a polynucleotide comprising SEQ ID NO:7 or 8 in "any cell or tissue", for reasons already of record in paper No:15.

Applicant argues that the claim is drawn to a method for diagnosing the presence of prostate cancer, by determining the levels of a polynucleotide comprising SEQ ID NO:7 or 8, or a protein expressed thereby in cells, tissues and bodily fluids in a patient and comparing these levels to a normal control. Applicant asserts that references related to altered expression in metastatic cancers as cited by the Examiner are not relevant to the predictability of the present invention drawn to diagnosing the presence of prostate cancer.

Applicant's arguments in paper No:18 have been considered but are found not to be persuasive for the following reasons:

The claim encompass a method for detecting metastasis prostate cancer, since prostate cancer could be either localized or metastatic prostate cancer, in view that the claims are drawn to a detection involving expression of SEQ ID NO:7 or 8 in any cell or any tissue other than prostate cancer tissue. Thus the claims are not enable because it is unpredictable that metastatic prostate cancer cells still overexpress or underexpress SEQ ID NO:7 or 8, in view of the teaching of Kibel et al, Ren et al, and Gingrich et al, all of record.

Further, the claim is not enable even if the claim is limited to a method for detecting primary or localized prostate cancer, because there is no correlation between overexpression or underexpression of SEQ ID NO:7 or 8 in prostate cancer tissue of a prostate cancer patient and said expression in any other tissue or cell of said patient. It is well known in the art that expression of a gene in different tissues is different and independent of each other. Therefore, overexpression or underexpression of SEQ ID

NO:7 or 8 in prostate cancer is not related to its expression in other tissues or cells. Further, overexpression or underexpression of SEQ ID NO:7 or 8 in prostate cancer tissue is an unpredictable event, and thus one cannot predict that SEQ ID NO:7 or 8 would similarly overexpressed in other tissues or cells.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone



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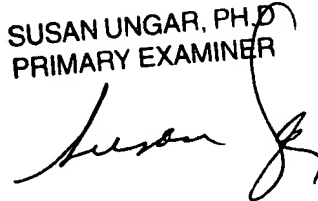
number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

September 02, 2003

SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Susan Ungar", written over the printed name and title.